

REMARKS

In the Office Action, the specification has been objected to; and claims 1-9 and 28-30 are rejected under 35 U.S.C. § 103. Applicants believe that the rejections are improper as discussed below.

At the outset, the Patent Office has restricted the present application to one of the following inventions under 35 U.S.C. §121 as indicated in the Office Action on pages 2 and 3: 1) Group I: Claims 1-9 and 28-30; Group II: Claims 10-27; Group III: Claims 31-38 and 49-53; and Group IV: Claims 39-48. During a telephone conversation between the Patent Office and Mr. Joseph P. Reagen on November 19, 2003 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-9 and 28-30.

Affirmation of the election of Group I, claims 1-9 and 28-30 is herein made with traverse. Contrary to the Patent Office position, Applicants believe that the alleged groups of invention are not so different in subject matter that an examination of all of claims 1-53 on the merits can be made without placing undue burden on the Patent Office. As even admitted by the Patent Office, claims 1-9 and 28-30 of Group I are drawn to a sensor for sensing ammonia in a fluid; claims 10-27 of Group II are drawn to a sensor for dialysis system; and claims 31-38 and 49-53 of Group III are drawn to a method of sensing ammonia in a dialysis system. Indeed, the claims in Groups I and II are even classified in the same class, namely, class 422. Further, claims 39-48 of Group IV are drawn to a method for performing dialysis that utilizes a membrane that changes a parameter in relation to the level of a component in the dialysate fluid wherein the component is ammonium or ammonia as further defined. Therefore, Applicants respectfully request that the restriction requirement be withdrawn.

With respect to the objection to the specification, Applicants respectfully submit that this objection is improper. Contrary to the Patent Office's position, Applicants believe that one skilled in the art can readily practice the claimed invention based on what is disclosed in the Specification, alone or in combination with what is of general knowledge and understanding to the skilled artisan. Indeed, the Patent Office is able to ascertain that the present invention relates to an ammonia sensor as depicted on figures 1-8, for example, according to an embodiment. See, Office Action, pages 3-4. Thus, Applicants respectfully submit that the objection to the specification should be withdrawn.

In the Office Action, claims 1-9 and 28-30 are rejected under 35 U.S.C. § 103. More specifically, claims 1-7, 9 and 28-30 are rejected in view of U.S. Patent No. 4,661,246 (“Ash”) and WO01/35057 A2 (“Khalil”); and claim 8 is rejected in view of Ash, Khalil and further in view of U.S. Patent No. 4,350,660 (“Robinson”). The Patent Office primarily relies on Ash and thus relies on Khalil and Robinson to remedy the deficiencies of same. Applicants believe that the obviousness rejections are improper.

Of the pending claims at issue, claims 1 and 28 are the sole independent claims. Claim 1 relates to a sensor for sensing ammonia in a fluid. The sensor includes a fluid flow path that has an optical window; a membrane that is positioned within the fluid flow path wherein the membrane exhibits a color indicative of the concentration of the ammonia in the fluid; and an optical reader positioned outside of the fluid flow path that can identify the color of the membrane through the optical window. Claim 28 relates to an ammonia sensor for dialysis system. The ammonia sensor includes a disposable unit that has a fluid flow path; an ammonia sensitive membrane inside of the fluid flow path; and a membrane reader positioned outside of the fluid flow path in sensing relationship with the membrane.

As supported in the specification on pages 13 and 14, the membranes of the sensors are capable of sensing a gas dissolved in solution, such as ammonia dissolved in dialysate solution. The ammonia sensing membranes can include a hydrophobic membrane that has a micro porous structure and a pH sensitive dye embedded within the microporous structure of the membrane. In this regard, the ammonia sensing membrane is capable of selectively detecting gaseous phase ammonia as the pH sensitive dye which is embedded within a surface of the microporous membrane structure composed of strands that are colorimetrically active in the presence of gaseous phase ammonia. It is suggested that the dye is embedded on the surface of the microporous structure defined by membrane strands within the microporous structure. In this regard, the dye can absorb to at least a portion of the surface of the microporous structure such that the dye remains intimately bound (e.g., embedded) within the microporous structure even as the membrane is subject to varying environmental conditions. The hydrophobic membrane material can be composed of a variety of different suitable materials, such as fluorine containing polymers including polyvinylidene difluoride.

Applicants believe that the cited art even if properly combinable is deficient with respect to the claimed invention. At the outset, the primary Ash reference is deficient with respect to a

pH sensitive hydrophobic membrane, let alone a hydrophobic membrane that has a microporous structure and a pH sensitive dye embedded within the microporous structure of the membrane as required by the claimed invention. Thus, on its own, Ash fails to disclose or suggest the claimed invention based on at least these reasons.

Further, Applicants do not believe that the remaining cited art can be relied on, even if properly combinable, to remedy the deficiencies of Ash. At the outset, Applicants question whether the Khalil reference can be combinable with Ash in the first case. In this regard, Ash merely relates to a monitor for detecting ammonia that includes a test strip positioned adjacent a membrane wherein the test strip is used to detect ammonium in the fluid. See, Ash, column 2, lines 59-68. In contrast, the Khalil reference relates to an ammonia-sensitive indicator dye for application to a PTFE substrate, such as a film. Why then would one skill in the art be inclined to combine the teachings of Ash with Khalil where Ash merely utilizes a test strip in contrast to the ammonia-sensitive indicator dye as disclosed in Khalil.

Even if combinable, Applicants do not believe that Khalil on its own can modify the deficiencies of Ash. Again, the present invention can utilize hydrophobic membranes wherein a pH sensitive dye is embedded within a microporous structure of same. An example of a hydrophobic membrane material includes a polyvinylidene difluoride as discussed above. In contrast, the primary focus of Khalil relates to a sensor composition that is made from an ammonia sensitive indicator dye and a solid phase, preferable a PTFE solid phase in a film form. Nowhere does Khalil disclose or suggest the membrane features of the claimed invention, particularly a hydrophobic membrane with a pH sensitive dye that is embedded within the microporous structure of same as previously discussed. Therefore, Applicants believe that one skill in the art would not be inclined to modify Ash in view of Khalil to arrive at the claimed invention based on at least these reasons as discussed above.

With respect to the Robinson reference, the Patent Office merely relies on Robinson for its alleged disclosure relating to an infra-red emitter for calibrating ammonia gas background. See, Office Action, page 6. Clearly, this is insufficient to overcome the deficiencies of Ash, alone or in combination with Khalil, as discussed above.

Based on at least these reasons, Applicants believe that the cited art fails to disclose or suggest the claimed invention. Therefore, Applicants respectfully submit that the cited art, even if combinable, fails to render obvious the claimed invention.

Accordingly, Applicants respectfully request that the obviousness rejection be withdrawn.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

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